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004/015

Docket No. M-1107 US

Response to Final Office Action

Overview

5 Applicant amended independent claim 1. Applicant previously cancelled claims 13-20, without prejudice. Applicant is referring to Lantz, U.S. Patent Publication Number 2006/0120432 A1 by paragraph number when responding as Applicant. Sato U.S. Patent 3,738,173 is referred to as Sato. Makita U.S. Patent 5,340,215 is referred to as Makita. The Applicant affidavit provides further support that the Sato reference is 10 not teaching or disclosing the claimed invention. Applicant will respond to the Office Action by paragraph number.

Background

15 Applicant's invention claims at least one finger ejects the probe cover from the probe without exposing the ejecting finger to possible contamination from a patient's body part. The exterior surface of the probe may become contaminated by use within a patient's ear with a protective cover. Possible contamination of the Applicant's ejection finger or probe shaft is avoided when the Applicant's cover shields the probe tip and ejection fingers, when the shaft is inserted into the ear to take a temperature 20 measurement.

As claimed, the Applicant's ejection finger moves distally toward a distal end of the probe, along the outer surface of the probe and the inner surface of the probe cover,

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the cover conceals the finger during use for taking a temperature measurement. The finger engages a proximal face at the inner surface of the probe cover as the finger moves distally along the probe to eject the probe cover. The Applicant's probe tip or shaft holding its probe cover is fixed to the thermometer housing.

5

Response to the Office Action**Paragraph 2 of the Office Action**

The Applicant respectfully requests paragraphs [0001], [0049], [0052] and [0055] be updated as requested below.

10 The Applicant respectfully requests paragraph [0001] which currently reads "This patent application incorporates by reference PCT Application No. PCT/US03/_____ Express Mail Label No. EV222416147US, filed in the U.S. Patent and Trademark Office on January 6, 2003, the entire contents of which is hereby incorporated by reference herein.", be replaced with "This patent application incorporates by reference PCT 15 Application No. PCT/US03/00256, Express Mail Label No. EV222416147US, filed in the U.S. Patent and Trademark Office on January 6, 2003, the entire contents of which is hereby incorporated by reference herein."

20 The Applicant respectfully requests paragraph [0049] which currently reads, "Referring to FIGS. 6 and 7, probe cover 32, similar to the probe covers disclosed in co-pending and commonly assigned PCT Application No. PCT/US03/_____ Express Mail Label No. EV222416147US, filed in the U.S. Patent and Trademark Office on January 6, 2003 has a distal end 54 that is substantially enclosed by a film 56. Film 56 is substantially transparent to infrared radiation and configured to facilitate sensing of

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ear wax, moisture and bacteria to prevent disease propagation.", **be replaced with**
"Referring to FIGS. 6 and 7, probe cover 32, similar to the probe covers disclosed in co-pending and commonly assigned PCT Application No. PCT/US03/00256 Express Mail Label No. EV222416147US, filed in the U.S. Patent and Trademark Office on January 5, 2003 has a distal end 54 that is substantially enclosed by a film 56. Film 56 is substantially transparent to infrared radiation and configured to facilitate sensing of infrared emissions by heat sensing probe 22. Film 56 is advantageously impervious to ear wax, moisture and bacteria to prevent disease propagation."

The Applicant respectfully requests that paragraph [0055] which currently reads
10 "Inner surface 34 of probe cover 32 engages outer surface 30 of heat sensing probe 34 for retention therewith. Inner protuberances 62 slide over ends 44 and are positioned for disposal within groove 42. This configuration provides sufficient retention between heat sensing probe 34 and probe cover 32 so that probe cover 32 is retained with heat sensing probe 34 and probe cover 32 during temperature measurement of the subject.
15 Thus, the retention strength of inner protuberances 62 with heat sensing probe 22 must be overcome for proper removal and ejection of probe cover 32 from heat sensing probe 22. It is contemplated that probe cover 32 may include other retention structure for mounting probe cover 32 with heat sensing probe 22, similar to those disclosed in co-pending and commonly assigned PCT Application No. PCT/US03/_____ Express
20 Mail Label No. EV222416147US, filed in the U.S. Patent and Trademark Office on January 6, 2003.", **be replaced with** "Inner surface 34 of probe cover 32 engages outer surface 30 of heat sensing probe 34 for retention therewith. Inner protuberances 62 slide over ends 44 and are positioned for disposal within groove 42. This configuration

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provides sufficient retention between heat sensing probe 34 and probe cover 32 so that probe cover 32 is retained with heat sensing probe 34 and probe cover 32 during temperature measurement of the subject. Thus, the retention strength of inner protuberances 62 with heat sensing probe 22 must be overcome for proper removal and 5 ejection of probe cover 32 from heat sensing probe 22. It is contemplated that probe cover 32 may include other retention structure for mounting probe cover 32 with heat sensing probe 22, similar to those disclosed in co-pending and commonly assigned PCT Application No. PCT/US03/00256 Express Mail Label No. EV222416147US, filed In the U.S. Patent and Trademark Office on January 6, 2003."

10 The Applicant respectfully requests that paragraph [0052] which currently reads "Body 58 defines inner protuberances 62 projecting from inner circumferential surface 34 and being proximally spaced from distal end 54. Inner protuberances 62 have an elliptical configuration including a width c (FIG. 7 shows $\frac{1}{2}$ c due to the cross-section view) that is relatively larger than a height d. Inner protuberances 62 have a radial 15 curvature projecting a thickness e from inner circumferential surface 34 for engaging heat sensing probe 22. Inner protuberances 62 facilitate retention of probe cover 20 with heat sensing probe 34. Inner protuberances 54 provide air gap 55 (FIG. 3) of separation between heat sensing probe 22 and the tympanic membrane. This configuration minimizes undesired heating of heat sensing probe 22. It is contemplated 20 that one or a plurality of inner protuberances 62 may be used. Longitudinal ribs 36 and inner protuberances 62 may be variously dimensioned according to the particular requirements of a temperature measurement application.", be replaced with "Body 58 defines inner protuberances 62 projecting from inner circumferential surface 34 and

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being proximally spaced from distal end 54. Inner protuberances 62 have an elliptical configuration including a width c (FIG. 7 shows $\frac{1}{2}$ c due to the cross-section view) that is relatively larger than a height d. Inner protuberances 62 have a radial curvature projecting a thickness e from inner circumferential surface 34 for engaging heat sensing probe 22. Inner protuberances 62 facilitate retention of probe cover 20 with heat sensing probe 34. Inner protuberances 54 provide air gap 55 (FIG. 3) of separation between heat sensing probe 22 and the tympanic membrane. This configuration minimizes undesired heating of heat sensing probe 22. It is contemplated that one or a plurality of inner protuberances 62 may be used. Longitudinal ribs 36 and inner protuberances 62 may be variously dimensioned according to the particular requirements of a temperature measurement application." be replaced with "Body 58 defines inner protuberances 62 projecting from inner circumferential surface 34 and being proximally spaced from distal end 54. Inner protuberances 62 have an elliptical configuration including a width c (FIG. 7 shows $\frac{1}{2}$ c due to the cross-section view) that is relatively larger than a height d. Inner protuberances 62 have a radial curvature projecting a thickness e from inner circumferential surface 34 for engaging heat sensing probe 22. Inner protuberances 62 facilitate retention of probe cover 20 with heat sensing probe 34. Inner protuberances 62 provide air gap 55 (FIG. 3) of separation between heat sensing probe 22 and the tympanic membrane. This configuration minimizes undesired heating of heat sensing probe 22. It is contemplated that one or a plurality of inner protuberances 62 may be used. Longitudinal ribs 36 and inner protuberances 62 may be variously dimensioned according to the particular requirements of a temperature measurement application."

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Paragraph 3 of the Office Action

The Applicant amended claim 12 to correct the deficit rendering claim 12
5 indefinite.

Paragraph 5 of the Office Action

The Office Action rejected claims 1-2, 4-12 under 35 U.S.C. 102(b) as anticipated
10 by or, in the alternative, under 35 U.S.C. 103(a) as obvious under Sato (US Patent No.
3,738,173).

The Applicant respectfully suggests Sato neither anticipates nor renders the
claimed invention obvious in view of Sato based on the teachings of Sato. Sato's
15 alleged finger 13c is not capable of movement or moves under a force applied by a
user, as suggested at page 3, lines 6-8 and 14-15 of the Office Action. Figure 3 of Sato
shows the operation for ejecting the cover. The user depresses the button 15, in Sato,
while holding the collar 13 with her fingers under the end cap 25. The force applied at
15 moves the probe shaft through the concentric opening at collar 13. The shaft moves
20 the probe cover off the retaining means 19 at the collar 13. The alleged fingers 13c do
not move, they are fixed to the collar which is stationery during the probe cover ejection
operation.

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Furthermore, the Office Action at page 4 provides italicized text which states, "*It is noted, that in ejecting the probe cover, one can push down on the end cap 25 so that the fingers 13c strike the shoulder 12d of the probe cover 12 and thereby push off the probe cover 12.*" The Applicant would like the Examiner to review the Inventor affidavit, 5 in response to your note repeated above and located at page 4 of the Office Action.

The inventor affidavit takes the position that by pushing on the Sato end cap 25, the single assembly is moved along the probe shaft without dislodging its probe cover 12 from the collar 13 retaining means 19. The single assembly is formed when the user installs the cover 12 over the shaft 20, the cover is retained on the collar 13 by the 10 retaining means 19 thereby forming the single assembly of the collar and cover in Sato. The Sato shaft 20 must move to eject the cover or to install the cover because the Sato cover is secured to the collar/retaining 13/19 means. The cover is retained on the probe shaft in the present invention. In the present invention, a finger [26, 28] ejects the cover [32] off the probe [22] shaft and by contrast in Sato its shaft 14 ejects a cover 12 off the 15 Sato collar 13. The Sato shaft moves through an opening in its collar.

Sato can not anticipate under 102 because in the present invention the function imparted by its structure and the structure itself are both different from Sato. First, Sato moves its probe shaft, and by contrast, the present invention moves a finger [26, 28], to eject the installed probe cover [32]. Next, the present invention retains its cover to the 20 probe shaft [22], and by contrast, Sato retains its cover to a collar 13 not structurally connected to the probe shaft. See Inventor Affidavit.

Sato is not obvious as it does not teach or disclose the claimed invention because in the present invention structural differences result in a different operation to

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eject or install the probe cover as compared to Sato and discussed above. There is no support in Sato that would lead a person using common sense to keep the probe shaft stationary and to use the shaft to retain the cover, as found in the present invention. See Inventor Affidavit.

5 The Applicant respectfully suggests that Sato does not anticipate or render obvious claim 5 thru claim 9 of the present invention because the alleged Sato fingers 13c are not moveable. See Inventor Affidavit.

Response to Paragraph 7 of the Office Action

10 Claims 1-12 are rejected under 35 U.S.C. 103(a) as obvious over Sato in view of Makita.

15 The Applicant respectfully disagrees that Makita teaches its fingers 7 move along the inside of the probe cover, as claimed in the present invention, to eject the cover. The Makita eject fingers strike the proximal face at the outer edge of the probe cover, on the outside of the probe cover 9 not inside the cover 9, to eject the cover 9 from the retaining groove on the Makita shaft. This is shown at the Applicant's annotated finger Fig 4 of Makita. By contrast, the Examiner is referred to Figure 9 of the present
20 invention as explained in paragraphs [0056-57] and which shows the finger [26, 28] striking a surface at the inside of the probe cover to eject the cover. The eject finger and shaft are kept sanitary with a probe cover covering the shaft and eject fingers when the device is used as intended, in the present invention. See Annotated Makita Figure 4

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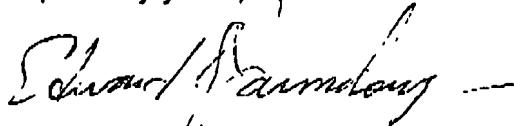
with its cover installed the probe 4 and fingers 7 are exposed to germs and other sources of contamination during use.

Summary

5 Applicant respectfully requests an Examiner interview, if the above amendments and the supporting Inventor Affidavit do not place this application in a condition of allowance. Applicant authorizes the Commissioner for Patents to charge Deposit Account number 190254 for any late fees or charges necessary to avoid abandonment. I can be reached direct at (508) 261-8476 or Edward.jarmolowicz@tycohealthcare.com.

10

Respectfully yours,



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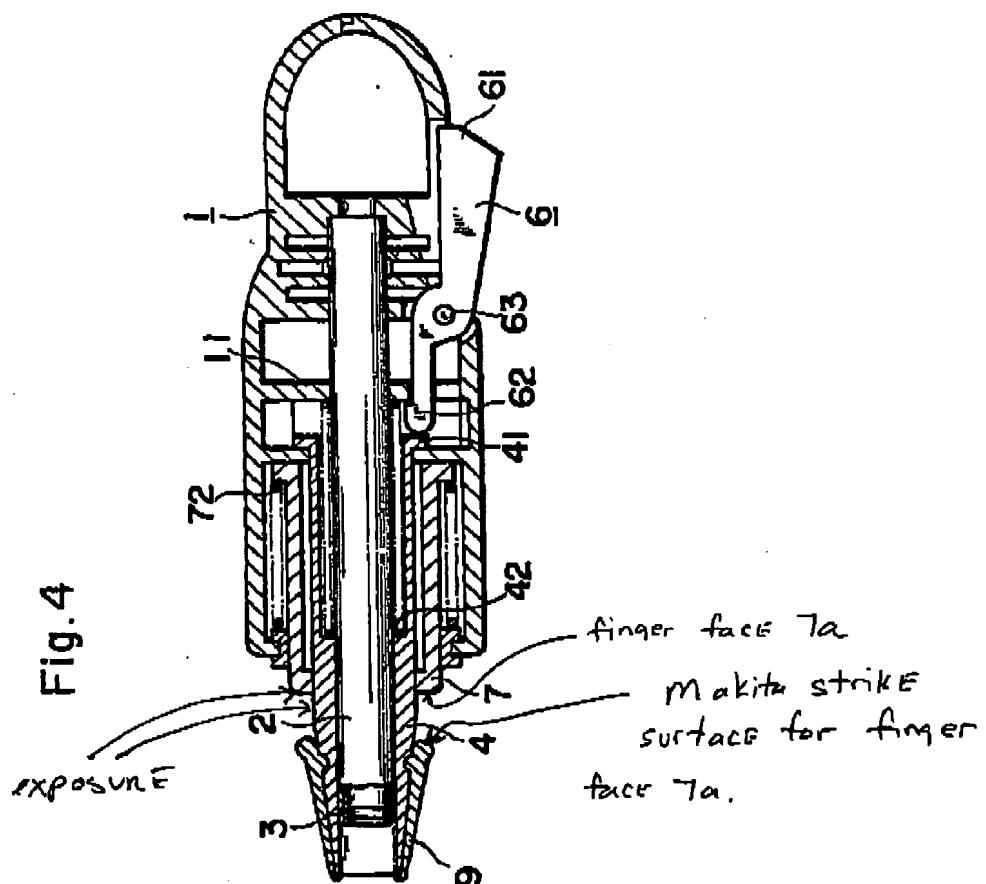
U.S. Patent

Aug. 23, 1994

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Applicant's Annotated Fig 4.



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Commissioner for Patents
Attention of Examiner Towa
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313

Dear Examiner:

I am an inventor of U.S. Patent Application Serial No. 10/538,543.

My invention answers a long understood need, in the medical field, to reduce the spread of germs from patient to patient when using a medical device designed for repeated use. Prior art thermometers expose a portion of the probe shaft because prior art probe covers, that I am aware of, do not completely cover the probe shaft. The exposure of the shaft in close proximity to a body part, such as when placed into a patient's ear or mouth, allows for human hair, skin and bodily fluids to collect at the exposed shaft over repeated uses by a nurse.

To prevent the transfer of germs from the exposed portions at the thermometer shaft to the next patient, I designed the probe shaft and ejection mechanism, so the probe cover would cover the shaft and ejection fingers. This provided a sanitary barrier between the shaft/ejection fingers and human body parts to reduce the spread of germs. After use, the probe cover is ejected from the probe tip and disposed in a medical waste container. The next design issue was to eject the installed cover from the retaining means for the cover to the shaft, without exposing the ejection mechanism to the body parts of a patient or to the used (dirty) probe cover. I designed the cover to overlay the ejection mechanism. My ejection mechanism moves a finger under the force imparted by depressing a button, the finger moves beneath the cover, distally along the surface of the probe shaft, and the finger strikes a pre-positioned protrusion at the inner surface of the cover, which releases the cover from the retaining means at the probe shaft.

I have reviewed U.S. Patent No. 3,738,173 to Sato. Sato ejects its probe cover using the probe shaft to dislodge the cover from a retaining means formed in a collar. The collar is positioned around the probe shaft. The retaining means 19 holds the cover onto the collar and over the probe shaft when the cover is installed for taking a temperature measurement. The collar is concentric around the probe shaft of Sato. The Sato shaft moves up through the opening in the collar during cover insertion, and the shaft is pushed down through the collar opening during cover ejection. To remove or eject the used cover from the probe, the user depresses a button forcing the probe shaft distally (away from the user). The force imparted via the button releases the cover from the retaining means at the collar, not at the probe shaft of Sato and the previously compressed spring is released, imparting additional energy to propel the cover beyond the tip of the probe shaft, so the user need not physically remove the dirty cover from the probe shaft.

My invention has a button for dislodging the cover from a retaining means. Likewise, a

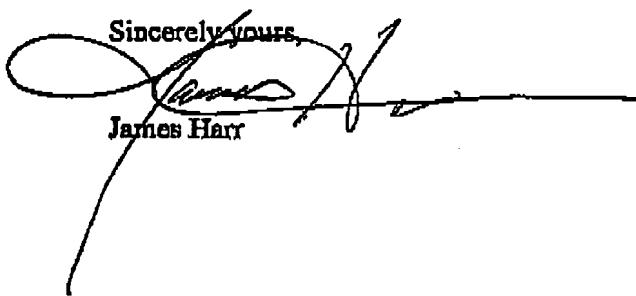
spring is released to help propel the installed cover beyond the distal end of the probe shaft or tip, so the user does not need to handle the dirty cover.

The difference between Sato and my invention is that in Sato, its button moves the probe shaft distally to eject the probe cover. In my invention, the button moves a finger distally along the outer surface of the probe tip beneath the cover. The moving finger dislodges the cover from the retaining means at the probe shaft.

My invention is structurally different from Sato. My finger moves distally along the shaft while in Sato, the proposed finger at collar position 13c remains fixed under the energy delivered by depressing the button. The intended and proper use of the Sato probe is shown at Figure 3. In my opinion, depressing end cap 25 to eject the probe cover of Sato is not possible, as described below. Applying a force by pressing on end cap 25, of Sato, moves the cover, collar and spring as a single assembly along the concentric probe shaft. The cover and collar move as a single assembly because the force imparted at the end cap is not transmitted to the probe shaft, to move the probe shaft distally to eject the probe cover off the retaining means 19 attaching the cover to the collar 13 in Sato. As described above, depressing the button of Sato imparts the pushing force of the human finger to the Sato shaft to overcome the retaining means of Sato, which holds the cover onto the collar. There is no structure to transmit the energy, applied at the end cap 25, to the probe shaft as the Sato shaft freely moves within the concentric opening at the collar. Since the collar is attached to the probe cover at the retaining means 19 the cover is not dislodged by applying a force at end cap 25.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Sincerely yours,



James Harr